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09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/879,216

Applicant(s)

RICHARD, ROBERT E.

Examiner

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 4, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Examiner notes with appreciation Applicant's election of Group I, claims 1-15, in paper 6.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is incomplete. The claim reads "...the therapeutic substantially dissolves in the supercritical fluid upon." It is not clear upon what the therapeutic dissolves.

Claim 7 is unclear. Application of a vacuum force to a chamber containing the medical device and supercritical fluid would render the supercritical fluid sub-critical due to the lack of pressure. The claim would be more clear if Applicant stated that the vacuum force was used, for example, after the coating method to remove excess supercritical fluid or before the coating method to evacuate the chamber of ambient air, etc.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Greiner (EP 0 405 284 A2).

Greiner teaches a method of coating a catheter medical device comprising creating a saturated solution of a pharmaceutical in a supercritical fluid and contacting the saturated solution to a medical device, wherein a subsequent reduction of pressure transfers the pharmaceutical from the supercritical fluid to the medical device (abstract; paragraph bridging columns 1 and 2).

Regarding claim 4, Greiner teaches immersion of the catheter in the saturated solution, which would qualify as exposing the catheter to a "bath" of the solution (col. 1, line 55).

Regarding claim 5, the therapeutic dissolves in the supercritical fluid, as stated above.

Regarding claim 6, it appears that the solution of Greiner meets the definition of a colloid, in that particles of the agent are mixed with a solvent to form the solution.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner.

Greiner teaches that which is disclosed above.

While Greiner teaches immersion of the medical device into the therapeutic solution, he fails to specifically teach spraying of the solution onto the medical device. However, it is Examiner's position that the interchangeability of dipping and spraying as coating techniques is well-known in the art of chemical coating. It would have been obvious to one of ordinary skill in the art to substitute one method for another with the expectation of similar, successful results because both methods are known to provide uniform coatings in a simple manner.

Regarding claims 7 and 9, Greiner fails to specifically teach recycling of the therapeutic agent.

First, Examiner notes that maintenance of a supercritical fluid at supercritical temperature and pressure inherently requires the use of a coating chamber.

Regarding the recycling operation, Examiner notes that Greiner's method of immersing a catheter into a saturated solution of a therapeutic agent will not result in attachment of

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all therapeutic agent that is present in solution to the surface of the catheter. After immersion, excess supercritical fluid, with therapeutic agent dissolved there, will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would recycle the excess solution to recover the expensive pharmaceutical agents therein for a subsequent coating operation. In recovering the solution from the coating chamber, a pump would be required to move the solution. Creating a pressure differential, using a vacuum, would have been obvious to one of ordinary skill in the art desiring to move the solution from the chamber to a recycling location.

Regarding claim 11, Greiner teaches a wide variety of catheter substrates to be coated in the method of his invention, including those used in the cardiovascular system, which appear to be "angio-catheters" or those which are inserted peripherally to be used centrally, as required by the claim.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Hossainy (US 6,153,252).

Greiner teaches that which is disclosed above. Additionally, Greiner teaches the use of supercritical carbon dioxide as the fluid of his invention, as is required by claim 10.

Greiner further teaches the use of such pharmaceutical therapeutic agents as antibiotics and growth factors (col. 4), among many. However Greiner fails to specifically teach the use of the specific paclitaxel agent required by Applicant.

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Hossainy teaches the use of antibiotics, growth factors, and paclitaxel, among others, as coatings for implantable medical devices.

Since Greiner and Hossainy teach the use of therapeutic agents on implantable medical devices and Hossainy teaches the suitability of paclitaxel for such a coating, Hossainy would have reasonably suggested the use of paclitaxel as the therapeutic agent for coating onto the medical device of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Greiner to coat Greiner's medical device with paclitaxel because it would have been expected that paclitaxel would serve as a beneficial agent when used *in vivo* on a medical device for controlled elution within the vicinity of the implantable device.

9. Claims 2, 8, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Cook et al. (US 5,916,585).

Greiner teaches that which is disclosed above regarding the use of supercritical fluid to deposit pharmaceutical agents on implantable medical devices.

What Greiner fails to specifically teach is the use of a carrier coating in addition to the pharmaceutical agent.

Regarding claims 2 and 12, Cook et al. teach coating implantable medical devices, such as vascular grafts or stents, with a hydrophilic polymer layer, followed by a bioactive species attached to the polymer layer by functional groups (abstract). The polymer

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layer of Cook acts as a carrier for the bioactive species. The bioactive species may be a drug or pharmaceutical agent (col. 7, lines 17-21; examples 15 and 16).

Since Greiner teaches application of a therapeutic agent onto an implantable vascular device and Cook teaches the use of a polymeric carrier layer to be used in conjunction with a pharmaceutical agent on an implantable vascular graft or stent, Cook would have reasonably suggested the use of a polymer carrier in the method of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Cook in the method of Greiner because it would have been expected that the use of Cook's carrier layer would have provided the device of Greiner with a more firmly attached pharmaceutical agent and a more hydrophilic coating.

Regarding claim 8, Cook additionally teaches the use of supercritical carbon dioxide as a suitable solvent for application of the hydrophilic polymer carrier layer of his invention. Cook is combinable with Greiner for those reasons outlined above regarding claims 2 and 12. Additionally, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply Cook's polymer carrier layer in supercritical carbon dioxide at the same time as Greiner's pharmaceutical agent in supercritical carbon dioxide with the expectation of successful results because the combined teachings of Greiner and Cook indicate that supercritical carbon dioxide is a suitable solvent for the polymer carrier layer and the pharmaceutical agents of their inventions. It would have been obvious to one of ordinary skill in the art to use a single supercritical fluid



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processing step for both the carrier and the drug instead of the more time-consuming, thus costlier, 2-step method.

Regarding claims 13-14, Greiner teaches immersion as the application technique. As outlined above, spraying is an obvious variation of immersion/flooding/dipping in the chemical coating art.

Greiner teaches that the supercritical carbon dioxide solvent acts to swell the polymer catheter substrate of his invention, as is required by claim 15 (abstract).

### ***Conclusion***

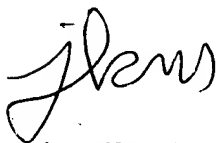
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Albano teaches the use of supercritical fluid technology for simultaneously depositing a pharmaceutical agent and polymer. Subramaniam et al. is cited for teaching the desirability of recycling the components of a supercritical fluid method. Mehta is cited for teaching the coating of medical devices using supercritical fluids.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
September 27, 2002



SHRIVE P. BECK  
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